this rejection. Applicants will initially discuss the Winston reference and the ways in which each independent claim distinguishes from that reference.

The Applied Reference

Winston discloses a stent and placement system that includes a spool 12, one or more flanges 14 formed on the spool 12, and a stent 10 adjacent to and abutting each flange 14. Stent 10 is formed from a solid sheet 11 that is wrapped several times to provide several layers. Spool 12, its flange(s) 14, and stent(s) 10 are placed within an outer elongated sheath 20. The entire outer surfaces of stent(s) 10 and flange(s) 14 completely contact the inner surface of sheath 20. No gap, or clearance, exists between flange(s) 14 and sheath 20. In addition, Winston has no teaching or suggestion of flanges 14 have varying stiffness, of a translucent distal region on sheath 20, or a marker band on spool 12.

Claims 1, 10, 14, 24, 34, and 44

Independent claims 1, 10, 14, 24, 34, and 44 each recite either an inner elongated structure that includes at least one marker band proximate a stent accommodating area, an outer tubular structure having a translucent region at its distal end, or a combination of these recitations. As discussed in the specification, these structural elements allow a user to view the distal portion of the inner structure carrying a stent when that distal portion is near the distal end of the outer tubular structure. This can signal to the user that the stent is about to be deployed.

Specifically, claim 14 recites an inner elongated structure for a stent delivery device that includes, among other things, a stent accommodating area on its distal end

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and at least one marker band proximate the stent accommodating area. Claim 24 recites similar recitations.

Claim 10 recites a system for delivering a stent including, among other things, an outer tubular structure having a translucent region at its distal end. Claim 44 recites a method of deploying a stent that recites a delivery system having similar recitations.

Claim 1 is directed to a system for delivering a stent including, among other things, an outer tubular structure having a translucent region at its distal end, and an inner elongated structure having a stent accommodating area on its distal end and at least one marker band proximate the stent accommodating area. Claim 34 recites a method of deploying a stent that recites a delivery system having similar recitations. Claim 34 also includes the step of viewing the marker band when the marker band is beneath the translucent region.

As discussed, Winston has no teaching or suggestion of a marker band on spool 12, a translucent distal region on sheath 20, or viewing a marker band of an inner elongated structure when it is beneath a translucent region of an outer tubular structure. For at least these reasons, the Section 103 rejection based on Winston should be withdrawn.

Moreover, the Examiner fails to address at least the claim recitation of a translucent region on a distal end of the outer tubular structure. This recitation appeared in original claims 10 and 44, and the Office Action lacked any explanation for the rejection. It is impossible therefore for Applicants to respond to this obviousness rejection, and Applicants request a more definite statement from the Examiner or an indication that claims including this recitation are allowable.

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Claims 5, 19, 29, and 39

Claim 5 recites a system for delivering a stent including, among other things, an inner elongated structure having a plurality of external tubular structure contact areas projecting from its surface. Each of the contact areas is separated from the others, and the durometer increases for each subsequent contact area from the distal end to the proximal end. Claims 19, 29, and 39 recite similar recitations. As discussed in the specification, this claim feature promotes flexibility in the delivery system near the distal end where the device may require a greater degree of precision in winding through tortuous anatomy.

In the Office Action, the Examiner acknowledges that Winston fails to disclose this claimed arrangement but alleges that "making the Winston et al. inner tubular structure of increasing durometer from the distal end to the proximal end, in order to enable it to flex more easily at its distal end as it traverses tortuous blood vessels would have been obvious since it is well known to so construct catheters and other devices inserted within blood vessels for this reason." (See Office Action, pgs. 2-3.)

Nothing in Winston suggests providing multiple flanges 14 of differing stiffness so that spool 12 flexes more easily. To the contrary, the depiction in the Figures of very narrow flanges 14 suggests that varying the stiffness of flanges 14 would have little or no effect on the flexibility of the spool 12.

Moreover, in rejecting claim 5, the Examiner asserts that it is "well known" to construct catheters with a number of contact areas of increasing durometer from the distal end to the proximal end. The Examiner provides no support for this allegation. M.P.E.P. § 2144.03 states:

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> If the applicant traverses such an assertion the examiner should cite a reference in support of his or her position.
>
> When a rejection is based on facts within the personal knowledge of the examiner, the data should be stated as specifically as possible, and the facts must be supported, when called for by the applicant, by an affidavit from the examiner.

Applicants respectfully request that the Examiner provide the evidence required under this Section of the M.P.E.P. so that Applicants can properly respond to the rejection.

Claims 13 and 46

Claim 13 is directed to a system for delivering a stent into an anatomical structure including, among other things, a gap between an external surface of an external tubular structure and an interior surface of the outer tubular structure. Claim 46 recites a method having similar recitations.

Winston fails to disclose such an arrangement and expressly teaches away from this arrangement. As the Examiner states on page 2 of the Office Action, flange 14 of spool 12 slides against the interior surface of sheath 20 since they are shown as contacting one another in Figures 1, 2, and 4. No gap exists between flange 14 and sheath 20. For at least these reasons, the Section 103 rejection based on Winston should be withdrawn.

In view of these amendments and remarks, Applicants request the reconsideration of this application and the allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

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Respectfully submitted,

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Dated: January 10, 2003

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APPENDIX TO AMENDMENT

Amendments to the claims:

1. (Amended) A system for delivering a stent into an anatomical structure, the system comprising:

an outer tubular structure having a proximal end, [and] a distal end, and a translucent region at its distal end;

an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

a stent accommodating area on the distal end of the inner elongated structure; [and]

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area able to frictionally [sliding] slide against an interior surface of the outer tubular structure; and

at least one marker band on the inner elongated structure proximate the stent accommodating area.

5. (Amended) A system for delivering a stent into an anatomical structure, the system comprising:

an outer tubular structure having a proximal end and a distal end;

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an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

a stent accommodating area on the distal end of the inner elongated structure;

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area frictionally sliding against an interior surface of the outer tubular structure, wherein the external tubular structure contact area on the inner elongated structure comprises a plurality of external tubular structure contact areas projecting from the surface of the inner elongated structure, wherein each external tubular structure contact area on the inner elongated structure is separated from other external tubular structure contact areas, and [The system of claim 4,] wherein each subsequently proximal external tubular structure contact area on the surface of the inner elongated structure increases in durometer from the distal end to the proximal end of the inner tubular structure.

10. (Amended) A system for delivering a stent into an anatomical structure, the system comprising:

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an outer tubular structure having a proximal end and a distal end [The system of claim 1], wherein the outer tubular structure has a translucent region at its distal end;

an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

a stent accommodating area on the distal end of the inner elongated structure; and

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area frictionally sliding against an interior surface of the outer tubular structure.

13. (Amended) A system for delivering a stent into an anatomical structure, the system comprising:

an outer tubular structure having a proximal end and a distal end;

an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

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a stent accommodating area on the distal end of the inner elongated structure;

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area able to frictionally slide against an interior surface of the outer tubular structure; and [The system of claim 1, further comprising:]

a gap between an external surface of the [inner elongated] external tubular structure and the interior surface of the outer tubular structure.

14. (Amended) An inner elongated structure for a tubular stent delivery device used in deploying a stent into an anatomical structure, the inner elongated structure comprising:

an elongated structure;

a stent accommodating area on a distal end of the elongated structure and shaped to receive a constrained length of a stent; [and]

an engagement area projecting from the surface of the elongated structure and located proximal to the stent accommodating area, the engagement area able to frictionally slide against an interior surface of an outer tubular structure of a stent delivery device; and

at least one marker band on the elongated structure proximate the stent accommodating area.

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19. (Amended) An inner elongated structure for a tubular stent delivery device used in deploying a stent into an anatomical structure, the inner elongated structure comprising:

an elongated structure;

a stent accommodating area on a distal end of the elongated structure and shaped to receive a constrained length of a stent; and

an engagement area projecting from the surface of the elongated structure and located proximal to the stent accommodating area, the engagement area able to frictionally slide against an interior surface of an outer tubular structure of a stent delivery device, wherein the engagement area on the elongated structure comprises a plurality of engagement areas projecting from the surface of the elongated structure, wherein each engagement area on the elongated structure is separated from other engagement areas, and [The structure of claim 18,] wherein each subsequently proximal engagement area on the surface of the elongated structure increases in durometer from the distal end to the proximal end of the elongated structure.

24. (Amended) An inner elongated structure for a tubular stent delivery device used in deploying a stent into an anatomical structure, the inner elongated structure comprising:

an elongated structure;

stent accommodating means for accommodating a constrained length of a stent at a distal end of the elongated structure; [and]

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engagement means for frictionally engaging the elongated structure with an interior surface of an outer tubular structure of a stent delivery device; and ; and

marker means on the elongated structure within the stent accommodating means.

29. (Amended) An inner elongated structure for a tubular stent delivery device used in deploying a stent into an anatomical structure, the inner elongated structure comprising:

an elongated structure;

stent accommodating means for accommodating a constrained length of a stent at a distal end of the elongated structure; and

engagement means for frictionally engaging the elongated structure with an interior surface of an outer tubular structure of a stent delivery device, wherein the engagement means on the elongated structure comprises a plurality of engagement means projecting from the surface of the elongated structure, wherein each engagement means on the elongated structure is separated from other engagement means, and [The structure of claim 28,] wherein each subsequently proximal engagement means on the surface of the elongated structure increases in durometer from the distal end to the proximal end of the elongated structure.

34. (Amended) A method of deploying a stent with respect to an anatomical structure, the method comprising:

providing a stent delivery system, the system comprising:

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an outer tubular structure having a proximal end, [and] a distal end, and a translucent region at its distal end;

an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

a stent accommodating area on the distal end of the inner elongated structure accommodating a stent; [and]

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area frictionally sliding against an interior surface of the outer tubular structure; and

at least one marker band on the inner elongated structure proximate the stent accommodating area;

inserting the stent delivery system through an insertion point in a body until the distal ends of the external tubular structure and the inner elongated structure are in a position within the anatomical structure;

viewing the marker band when the marker band is beneath the translucent region;

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moving the outer tubular structure proximally while maintaining the position of the inner elongated structure, thus exposing the stent accommodating area and releasing at least part of the stent into the anatomical structure; and

continuing the proximal movement of the outer tubular structure with respect to the inner elongated structure until the stent is completely deployed into the anatomical structure; and

withdrawing the stent delivery system from the insertion point in the body.

39. (Amended) A method of deploying a stent with respect to an anatomical structure, the method comprising:

providing a stent delivery system, the system comprising:

an outer tubular structure having a proximal end and a distal end;

an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

a stent accommodating area on the distal end of the inner elongated structure accommodating a stent; and

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area able to frictionally slide against an interior surface of the outer tubular structure, wherein the external tubular structure contact

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area on the inner elongated structure comprises a plurality of external tubular structure contact areas projecting from the surface of the inner elongated structure, wherein each external tubular structure contact area on the inner elongated structure is separated from other external tubular structure contact areas, and [The method of claim 38,] wherein each subsequently proximal external tubular structure contact area on the surface of the inner elongated structure increases in durometer from the distal end to the proximal end of the inner tubular structure;

inserting the stent delivery system through an insertion point in a body until the distal ends of the external tubular structure and the inner elongated structure are in a position within the anatomical structure;

moving the outer tubular structure proximally while maintaining the position of the inner elongated structure, thus exposing the stent accommodating area and releasing at least part of the stent into the anatomical structure;

continuing the proximal movement of the outer tubular structure with respect to the inner elongated structure until the stent is completely deployed into the anatomical structure; and

withdrawing the stent delivery system from the insertion point in the body.

44. (Amended) A method of deploying a stent with respect to an anatomical structure, the method comprising:

providing a stent delivery system, the system comprising:

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an outer tubular structure having a proximal end and a distal end [The method of claim 34], wherein the outer tubular structure has a translucent region at its distal end;

an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

a stent accommodating area on the distal end of the inner elongated structure accommodating a stent; and

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area able to frictionally slide against an interior surface of the outer tubular structure;

inserting the stent delivery system through an insertion point in a body until the distal ends of the external tubular structure and the inner elongated structure are in a position within the anatomical structure;

moving the outer tubular structure proximally while maintaining the position of the inner elongated structure, thus exposing the stent accommodating area and releasing at least part of the stent into the anatomical structure;

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continuing the proximal movement of the outer tubular structure with respect to the inner elongated structure until the stent is completely deployed into the anatomical structure; and

withdrawing the stent delivery system from the insertion point in the body.

46. (Amended) A method of deploying a stent with respect to an anatomical structure, the method comprising:

providing a stent delivery system, the system comprising:

an outer tubular structure having a proximal end and a distal end;

an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

a stent accommodating area on the distal end of the inner elongated structure accommodating a stent;

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area able to frictionally slide against an interior surface of the outer tubular structure; and [The method of claim 44, wherein the stent delivery system further comprises:]

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a gap between an external surface of the [inner elongated] external tubular structure and the interior surface of the outer tubular structure;

inserting the stent delivery system through an insertion point in a body until the distal ends of the external tubular structure and the inner elongated structure are in a position within the anatomical structure;

moving the outer tubular structure proximally while maintaining the position of the inner elongated structure, thus exposing the stent accommodating area and releasing at least part of the stent into the anatomical structure;

continuing the proximal movement of the outer tubular structure with respect to the inner elongated structure until the stent is completely deployed into the anatomical structure; and

withdrawing the stent delivery system from the insertion point in the body.

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